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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/057,339 | 01/25/2002 | Teddy Kosoglou | CV01490K | 1512 |

24265 7590 04/11/2005

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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| EXAMINER |
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KANTAMNENI, SHOBHA

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| ART UNIT | PAPER NUMBER |
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1617

DATE MAILED: 04/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/057,339

Applicant(s)

KOSOGLU ET AL.

Examiner

Shobha Kantamneni

Art Unit

1617

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 March 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: _____.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See page 2.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s).
13. ☐ Other: _____.


**SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER**

Continuation of 11: The 35 USC 103 rejections are maintained for reasons of record in the Office action mailed on 01/27/2005 and those found below.

Applicant argues "Roseblum et al. do not suggest or disclose a combination of a compound of formula (I) (such as ezetimibe) with a cardiovascular agent selected from the group consisting of channel blockers, antihypertensive agents.....Chobanian et al. discloses that the antihypertensive agent captopril can be useful for treating atherosclerosis. Chobanian et al. therefore teaches away from the concept of use of two separate compounds.....Therefore, one skilled in the art would not be motivated by teachings of Rosenblum et al. and Chobanian et al.,". This argument is not persuasive. Rosenblum '966 teaches a method of treating atherosclerosis, comprising administering a combination of ezetimibe and a cholesterol biosynthesis inhibitor. Rosenblum further teaches that the risk factors associated for atherosclerotic coronary heart disease, include hypertension, serum cholesterol etc. Thus there is motivation to combine a compound of formula (I) with antihypertensive agent captopril with the expectation of obtaining a synergistic effect for the treatment of atherosclerosis because '966 teaches that hypertension and high serum cholesterol are risk factors for atherosclerosis.

Applicant argues "the rejection of claims 43-45 is based upon improper hindsight reconstruction". This argument is not persuasive. It is respectfully pointed out that Rosenblum teaches that the pharmaceutical compositions comprising compound of formula (I) can be prepared using conventional excipients and additives which include non-toxic compatible fillers, binders, disintegrants, buffers, preservatives, anti-oxidants, thickeners, emulsifiers etc. See column 21, lines 5-15. Thus there is motivation to add anti-oxidant, vitamin C, water soluble fiber etc. to the composition comprising a compound of formula (I), and an antihypertensive agent,